K060830

JUN 15 2006

SECTION 6 – 510(k) SUMMARY

Submitter's Name and Address:

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Raynham, MA 02767 USA

Contact Person

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Project Management Lead, Regulatory Affairs
DePuy Mitek
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Name of Medical Device

Device Regulation:
Fastener, Fixation, Non-Degradable, Soft Tissue
(21 CFR 888.3040)
Product code: HWC and MAI

Common/Usual Name: Interference Screw

Proprietary Name:
MILAGRO Interference Screw

Device Classification

In accordance with per 21 CFR 888.3040, interference screws are classified by the FDA as Class II Medical Devices.

Indications for Use

The MILAGRO Interference Screw is indicated for the fixation of soft tissue grafts or bone-tendon-bone grafts during cruciate ligament reconstruction surgeries of the knee. The 7, 8 and 9mm x 23mm screws are also indicated for: medial and lateral collateral ligament repair of the knee, proximal bicep tenodesis in the shoulder and distal bicep tenodesis in the elbow.

510(k) SUMMARY

Device Description	The MILAGRO Interference Screw is a cannulated, threaded, tapered fastener for use in interference fixation of soft tissue grafts or bone-tendon-bone grafts. The device is made from a copolymer of absorbable Poly(lactide-co-glycolide) (PLA PGA) compounded with beta-Tricalcium Phosphate (β-TCP) and is available in several sizes and varied lengths.
Substantial Equivalence	The MILAGRO Interference Screw is a commercially marketed device that was subject of K032717 (cleared March 31, 2004). When used for the proposed indications the device is substantially equivalent to the Arthrex Bio-Corkscrew Suture Anchor (K003227, cleared 1/8/2001).
Safety and Performance	The determination of substantial equivalence for this device was based on a detailed device description. Non-clinical laboratory testing was performed demonstrating that the device is safe and can be considered substantially equivalent to the predicate devices for the proposed new intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 2006

DePuy Mitek
% Ms. Ruth Forstadt
Project Management Lead, Regulatory Affairs
325 Paramont Drive
Raynham, Massachusetts 02767

Re: K060830
Trade/Device Name: MILAGRO Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MAI
Dated: March 24, 2006
Received: March 27, 2006

Dear Ms. Forstadt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240-276-0120). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____
Device Name: Milagro Interference Screw

Indications for Use:

The MILAGRO Interference Screw is indicated for the fixation of soft tissue grafts or bone-tendon-bone grafts during cruciate ligament reconstruction surgeries of the knee. Additionally, the 7, 8 and 9 mm x 23 mm screws will be indicated for: medial and lateral collateral ligament repair of the knee, proximal bicep tenodesis in the shoulder and distal bicep tenodesis in the elbow.

Prescription Use ____√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063530